

Application No. 09/743,612

### REMARKS

Reexamination and reconsideration in light of the foregoing amendment and the following remarks is respectfully requested.

Claims 1-16, 18, 20-24, 26 and 27 are pending in this application. Claims 17, 19, 25 and 28 have been canceled without prejudice or disclaimer. Claim 1, 3-7, 9-13, 15, 18, 20-24, 26 and 27 have been amended. No new matter has been added to the application. Support for the amendments can be found at pages 5, 6 and 8 of the specification and original claims 17, 19, 25 and 28.

Applicants note the Examiner's consideration of the art cited in the Information Disclosure Statement filed January 12, 2001, as acknowledged in the Office Action Summary. Applicants further note the Examiner's acknowledgment of Applicants' claim for foreign priority under 35 U.S.C. § 119 and receipt of the certified priority document.

### REJECTION UNDER 35 U.S.C. § 112.

Claims 1-28 stand rejected under 35 U.S.C. § 112, second paragraph, on the following grounds:

1. In claim 1, the Examiner found the phrase "can take on" to be vague and indefinite, and that it was not a positive recitation. The phrase has been amended to "is capable of." It is believed that by this amendment, the rejection is overcome.

2. The Examiner also found claims 1, 15 and 22 to be vague and indefinite "because it is unclear if the coloration level measuring means requires one of either an optical measurement or an image measurement or both" and "because it is unclear how the coloration is achieved." The measuring means can measure by optical means or by imaging means or it can

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be a combination of both. A person having ordinary skill in the art would have interpreted the claim accordingly. As for how the coloration is achieved, the coloration occurs as the result of (i) a specific reaction between a binding reagent and an analyte or (ii) between a binding reagent and a substance resulting from bonding between an analyte and a labeling agent. See page 2, lines 13-18 of the specification.

3. The Examiner questions "how the analyte can be detected without the use of a label." The analytes contained in the liquid sample and the labeling agent produce a complex, which causes specific reactions with the binding reagent thereby causing a coloration reaction. See page 2, lines 13-18 of the specification.

4. The Examiner found that the phrase "--like" in claim 3 renders the claim indefinite because the claim includes "elements not actually disclosed (those encompassed by "or the like")," thereby rendering the scope of the claim unascertainable. The Examiner points to other phrases such as "sheet-like", "dot-like" and "spots-like." The objected to phrases are not indefinite. The ordinary meaning of the term "like" as used in the objected to phrases means "the same or nearly the same (as in appearance, character, or quantity)." See *Webster's Ninth New Collegiate Dictionary*, Merriam-Webster Inc., Springfield, Mass., p. 692 (1989). For example, to be sheet-like means a sheet or an element that is the same or nearly the same in appearance or character as a sheet as understood by a person having ordinary skill in the art. Therefore, the phrase "--like" is not indefinite, but would have been understood by a person skilled in the art. For this reason, it is respectfully requested that the rejection be reconsidered and withdrawn.

5. The Examiner found that the term "can be" in claims 3, 10, 21, 22 and 27 is vague and indefinite because the phrase "is a conditional phrase and is not a positive recitation." The

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phrase has been amended to recite "is capable of." It is believed that by this amendment, the rejection is overcome.

6. The Examiner found that the phrase "all over" in claim 6 is vague and indefinite. The term has been deleted from the claim, thereby rendering the rejection moot.

7. The Examiner found claim 7 to be vague and indefinite "because it is unclear how a liquid sample can be moistened." The claim has been amended to recite that the wettable material is moistened with the liquid sample. Support for the amendment can be found at page 6, line 11 of the specification.

8. The Examiner found that the phrase "capable of" as recited in claim 9, 14, 15, 21, 22 and 27 to be vague and indefinite in that the phrase "is not a positive limitation but only requires the ability to so perform." Applicants respectively traverse this rejection. The ordinary meaning of "capable" is "having attributes ... required for performance or accomplishment." See *Webster's Ninth New Collegiate Dictionary*, Merriam-Webster Inc., Springfield, Mass., p. 203 (1989). As used in claim 9, for example, the labeling reagent has an attribute required for bonding with at least one analyte. A person having ordinary skill in the art would have understood the scope of the claim in terms of the ordinary meaning of "capable of." Substantially the same argument applies to claims 14, 15, 21, 22 and 27. Accordingly, the phrase "capable of" is not indefinite.

9. The Examiner found the phrase "a condition of" in claim 15 to be vague and indefinite because "[i]t is unclear what is considered to be a condition of coloration (i.e. a coloration change, an arrangement of color, an increase or decrease)." The objected to phrase has been deleted, thereby rendering the rejection moot.

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10. The Examiner found that the phrase "being taken on" and the term "subjecting" in claim 15 renders the claim vague and indefinite because, with respect to each, "[i]t is unclear what applicant intends." The objected to phrase and term have been deleted from the claim, thereby rendering the rejection moot.

11. The Examiner found the phrase "has a nature" in claim 22 to be vague and indefinite in that "[i]t is unclear what applicant is trying to encompass (i.e. does the binding reagent have a certain structure or does the binding reagent contain a label or is applicant referring to something else)?" The phrase has been deleted from claim 22, thereby rendering the rejection moot.

For all of the foregoing reasons, it is requested that the rejection of the claims under 35 U.S.C. § 112, second paragraph, be reconsidered and withdrawn.

#### REJECTIONS UNDER 35 U.S.C. § 102

Claims 1, 8, 9, 22 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Sommer et al. (U.S. Patent No. 5,569,608). The factual determination of anticipation requires the disclosure in a single reference of every element of the claimed invention. *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990); *In re Bond*, 910 F.2d 831, 832, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990); *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 677-678, 7 USPQ2d 1315, 1317 (Fed. Cir. 1988); *In re Marshall*, 578 F.2d 301, 304, 198 USPQ 344, 346 (CCPA 1978); *In re Arkley*, 455 F.2d 586, 587, 172 USPQ 524, 526 (CCPA 1972). Sommer is directed to a method of determining the concentration of an analyte in a test fluid by an immunochromatography technique. With such a technique, an antibody is used as the binding agent. The coloration occurs as the result of a competitive reaction or non-competitive reaction

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forming a sandwich complex. The labeling agent is a gold colloid reagent such as HSA:gold sol conjugate. Base claims 1 and 22 (claims 8 and 9 are dependent on claim 1) as amended require that each reaction layer includes a plurality of reaction areas within the reaction layer and that each reaction area retain a binding reagent. In addition, the claims require that the reaction area is in the shape of a spot or dot. Neither of these elements of the base claims is disclosed by Sommer. Accordingly, claims 1, 8, 9 and 22 are not anticipated by Sommer. It is respectfully requested that the rejection be reconsidered and withdrawn.

Claims 1, 2, 8, 9, 15 and 22 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Kuo et al. (U.S. Patent No. 6,183,972). Kuo et al. is directed to a method of determining the concentration of an analyte in a test fluid by an immunochromatography technique similar to Sommer, *supra*. Base claims 1, 15 and 22 (claims 2, 8 and 9 depend on claim 1) as amended require that the reaction layer includes a plurality of reaction areas within the reaction layer and that each reaction area retain a binding reagent. In addition, the claims require that the reaction area is in the shape of a spot or dot. Neither of these elements of the base claims is disclosed by Kuo et al. The Examiner concedes on page 7 of the Office Action that Kuo et al. do not teach reaction areas having a plurality of spots. Accordingly, claims 1, 2, 8, 9, 15 and 22 are not anticipated by the disclosure of Kuo et al. It is respectfully requested that the rejection be reconsidered and withdrawn.

#### REJECTIONS UNDER 35 U.S.C. § 103(a)

Claims 3, 4, 6, 7, 10, 12-14, 16, 18-21, 23 and 25-28 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kuo et al. in view of Chandler et al. (U.S. Patent No. 6,271,046). Claims 19, 25 and 28 have been canceled, thereby rendering the rejection as to these

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claims moot. The rejection is traversed as being improper. Claims 3, 4, 6, 7, 10 and 12-14 ultimately depend on base claim 1 while claims 16, 18, 20 and 21 ultimately depend on base claim 15 and dependent claims 23, 26 and 27 depend on base claim 22. All of the claims rejected are dependent claims. None of the base claims upon which these claims depend have been rejected. Accordingly, since the Examiner has not rejected base claims 1, 15 and 22 over the prior art relied upon, the claims which further limit the base claims cannot be rejected.

Assuming arguendo, that the Examiner intended to include the base claims in the rejection, Chandler et al. do not make up for the deficiencies of Kuo et al. Claims 1 and 22 as amended require that the reaction layer includes a plurality of reaction areas within the reaction layer, that each reaction area retain a binding reagent, and that the reaction area is in the shape of spots or dots. These features recited in the base claims are not disclosed or suggested by Kuo et al. or Chandler et al., either taken alone or in combination. The Examiner concedes on page 7 of the Office Action that neither Kuo et al. nor Chandler et al. teaches reaction areas having a plurality of spots. Accordingly, the teachings of the references fail to present a *prima facie* case of obviousness. It is respectfully requested that the rejection of claims 3, 4, 6, 7, 10, 12-14, 16, 18, 20, 21, 23, 26 and 27 as being obvious over the combined teachings of Kuo et al. and Chandler et al. be reconsidered and withdrawn.

Claims 5, 11, 17, 24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kuo et al. in view of Chandler et al. and Catt et al (U.S. Patent No. 6,235,241). Claim 17 has been rejected, thereby rendering the rejection as to this claim moot. The rejection is traversed as being improper. Claims 5 and 11 ultimately depend on base claim 1 while claim 24 depends on base claim 22. All of the claims rejected are dependent claims. None of the base claims upon

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which these claims depend have been rejected. Accordingly, since the Examiner has not rejected base claims 1 and 22 over the prior art relied upon, the claims which further limit the base claims cannot be rejected.

Assuming *arguendo*, that the Examiner intended to include the base claims in the rejection, neither Chandler et al. nor Catt et al. make up for the deficiencies of Kuo et al. Claims 1 and 22 as amended require that the reaction layer includes a plurality of reaction areas within the reaction layer, that each reaction area retain a binding reagent, and that the reaction area is in the shape of spots or dots. These features of the base claims are not disclosed or suggested by Kuo et al. or Chandler et al., either taken alone or in combination. The Examiner concedes on page 7 of the Office Action that neither Kuo et al. nor Chandler et al. do not teach reaction areas having a plurality of spots.

The Examiner relies on Catt et al. as disclosing "the detectable material in a precisely defined region (detection zone) can be placed in the form of a narrow line or dot ...." The claims require more than a single dot. There is no suggestion or motivation from the teachings of Catt et al. to employ a plurality of spots or dots or to provide for a plurality of reaction areas within a reaction layer as recited in Applicants' claims.

Accordingly, the combined teachings of Kuo et al., Chandler et al. and Catt et al. fail to present a *prima facie* case of obviousness. It is respectfully requested that the rejection of claims 5, 11 and 24 as being obvious over the combined teachings of Kuo et al., Chandler et al. and Catt et al. be reconsidered and withdrawn.

For the foregoing reasons, it is submitted that the claims 1-16, 18, 20-24, 26 and 27 are patentable over the teachings of the prior art relied upon by the Examiner. Accordingly,

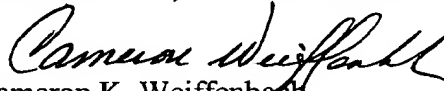
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favorable reconsideration of the claims is requested in light of the preceding amendments and remarks. Allowance of the claims is courteously solicited.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

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